URGENT VOLUNTARY RECALL: Hospital Level, October 01, 2024

Cisplatin Injection USP 1mg/mL (100 mL)

Accord Healthcare, Inc. ("Accord Healthcare") is voluntarily recalling **One lot** of Cisplatin Injection USP 1mg/mL (100 mL), at the Hospital Level.

This recall is being initiated because an out of specification result was observed during long term stability testing of Cisplatin Injection USP 1mg/mL at the 24-month time point. The out of specification result was observed in the any unspecified degradation impurity test during re-testing conducted for lot# P2202009 of Cisplatin Injection USP 1mg/mL. The specification limit for the any unspecified degradation impurity test is no more than 0.2%. During the testing of lot# P2202009, the result for the any unspecified degradation impurity test was observed at 0.2647% in the inverted condition and 0.2757% in the upright condition. This is considered as out of specification. As patient safety is our highest priority, we are taking immediate action to recall the affected product batch.

Please examine your inventory of Accord Healthcare's Cisplatin Injection USP 1mg/mL (100 mL) for the below listed lot number carefully. The product label for recalled products should have the following details, please refer to the enclosed product label included with this recall letter.

Item description	NDC #	Lot #	Exp. Date
Cisplatin Injection USP 1mg/mL (100 mL)	16729-288-38	P2202009	03/2025

Hospitals - Please perform the following activities:

- Examine your inventory immediately for the listed lot of Cisplatin Injection USP 1mg/mL (100 mL), P2202009.
- Immediately discontinue distribution of the recalled lot of Accord Healthcare's Cisplatin Injection USP 1mg/mL (100 mL), P2202009.
- Promptly complete the attached product recall response form and reply even if you have **NO** Product to return.
- If you do have Product to return, complete the attached product recall response form, quarantine the stock and follow the instructions given on the product recall response form.
- If you have further distributed this lot to other retailers, please immediately contact your customers, advise them of the recall and have them return their outstanding recalled stock to you. Return this stock as per the instructions on the attached product recall response form.

Your assistance is appreciated and necessary to prevent any potential health risk to the consumer.

Accord is working with Inmar Inc. to complete this recall. This recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is much appreciated.

Please complete and return the enclosed "PRODUCT RECALL RESPONSE FORM" as soon as possible, but no later than five business days from receipt of this letter.

Completed Product Recall Response form should be mailed, emailed, or sent via FAX to INMAR,
Attn: Inmar Rx Solutions, 3845 Grand Lakes Way, Grand Prairie, TX 75050.
INMAR Email: rxrecalls@inmar.com. FAX: 817-868-5362.

If you have any questions about the logistics for returning affected lots or other issues, please call Recall Services at 1-877-902-5659, Monday – Friday (excluding holidays), 9am to 5 pm EST.

INMAR will send you a Return Goods Authorization and shipping label. Appropriate credit for the returned product plus handling and shipping expenses will be issued to you upon receipt of the recalled product with the completed Return Goods Authorization. All recalled products returned without a Return Goods Authorization may delay the issuance of your credit.

We appreciate your assistance in this matter.

Sincerely,

Sabita Nair, RAC, ASQ-CPGP
Vice President – Regulatory Affairs
Accord Healthcare, Inc.
8041 Arco Corporate Drive, Suite 200
Raleigh, NC 27617
USA


Keep area blank &
varnish free
for overcoding Lot and EXP
& 2D Matrix 60 x 30 mm
(1 mg/mL)
100 mg/100mL
CISplatin Injection
SAFETY STICKERS ENCLOSED
STOP! VERIFY DRUG NAME & DOSE!
NDC 16729-288-38
51 4532 0 713531
INC5159_V1
accord
NDC 16729-288-38
STOP! VERIFY DRUG NAME & DOSE!
CISplatin doses greater than 100 mg/m² once every 3 to 4 weeks are rarely used. See Package insert.
CISplatin
Injection
100 mg/100mL
(1 mg/mL)
For Intravenous Use
100 mL
Multiple Dose Vial
Rx Only
Manufactured for:
Accord Healthcare Inc.,
Durham, NC 27703.
Manufactured by:
Intas Pharmaceuticals Limited,
Pharmez, Ahmedabad–382 213, India.
Mfg. Lic. No.: G/28/1336
N 3 16729 28838 5
Sterile
Each mL contains: 1 mg cisplatin and
9 mg sodium chloride in water for injection.
HCl and/or sodium hydroxide added to adjust pH.
The pH range of Cisplatin Injection is 3.5 to 5.0.
Usual dosage: See insert.
Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
DO NOT REFRIGERATE OR FREEZE CISPLATIN SOLUTION SINCE A PRECIPITATE OR CRYSTAL WILL FORM.
If precipitate or crystal observed inside the vial, keep it at recommended storage condition till clear solution obtained.
PROTECT FROM LIGHT.
This container closure is not made with natural rubber latex.
Unvarnished area for pasting

PRODUCT RECALL RESPONSE FORM

Product Recall Date: October 01, 2024 **Voluntary Recall: Hospital Level**

Item description	NDC	Lot	Exp. Date	Quantity Returning (In vials/units)
Cisplatin Injection USP 1mg/mL (100 mL)	16729-288-38	P2202009	03/2025	

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Customer Name _____DEA #_*_____

**DEA # is required, if not provided the processing of your form will be delayed.*

Address_____

City_____ State_____

Zip_____

Contact Name (please print)_____Telephone # _____

Contact Signature _____Date_____

If you did not purchase the product directly from the Manufacturer, please complete the following section.

Purchased from: Name _____DEA #_____

Address _____

City_____ State_____

Zip_____

Please check all appropriate boxes:

- ☐ I have read and understand the recall instructions provided in the letter.
- ☐ I have checked my stock and have quarantined inventory consisting of _____vials/units.

Any adverse events associated with recalled product?

☐Yes ☐ NO If yes, please explain: _____

Please describe your business: _____

I have checked my stock and:

_____Do not have any stock of recalled **items**.

OR

_____Have quarantined and listed in the box above the quantity of vials/units of **Cisplatin Injection USP 1mg/mL (100 mL)** and will be returning them to Inmar, as soon as possible.

Upon receipt of this Response Form, Inmar will issue return authorization label(s).

Please indicate the number of box labels needed:_____

Please fax this form to 1-817-868-5362 or E-mail at: rxrecalls@inmar.com. Questions - 1-877-902-5659.